

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE

PURDUE PHARMA L.P.,	)	
THE P.F. LABORATORIES, INC. and	)	
PURDUE PHARMACEUTICALS L.P.,	)	
	)	
Plaintiffs,	)	
	)	Civil Action No. _____
v.	)	
	)	
KV PHARMACEUTICAL COMPANY	)	
	)	
Defendant.	)	

**COMPLAINT**

Plaintiffs Purdue Pharma L.P., The P.F. Laboratories, Inc. and Purdue Pharmaceuticals L.P., for their Complaint herein, aver as follows:

**NATURE OF THE ACTION**

1. This is an action for patent infringement arising under the patent laws of the United States, Title 35, United States Code.

**JURISDICTION AND VENUE**

2. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331, 1338(a) and 2201.

3. This Court has personal jurisdiction over defendant because defendant resides in and, upon information and belief, is doing business in this Judicial District.

4. Venue is proper in this Judicial District under 28 U.S.C. §§ 1391(b) and (c) and § 1400(b).

### THE PARTIES

5. Plaintiff Purdue Pharma L.P. (“Purdue Pharma”) is a limited partnership organized and existing under the laws of the State of Delaware, having a place of business at One Stamford Forum, 201 Tresser Boulevard, Stamford, Connecticut 06901-3431. Purdue Pharma is an owner by assignment of the patents in suit identified in paragraph 9 below, and markets and sells in the United States the controlled-release oxycodone hydrochloride pain relief medication OxyContin® Tablets (“OxyContin®”).

6. Plaintiff The P.F. Laboratories, Inc. (“P.F. Labs”) is a corporation organized and existing under the laws of the State of New Jersey, having a place of business at 700 Union Boulevard, Totowa, New Jersey. P.F. Labs is an owner by assignment of the patents in suit identified in paragraph 9 below and manufactures OxyContin® in the United States.

7. Plaintiff Purdue Pharmaceuticals L.P. (“Purdue Pharmaceuticals”) is a limited partnership organized and existing under the laws of the State of Delaware, having a place of business at 4701 Purdue Drive, Wilson, North Carolina 27893. Purdue Pharmaceuticals is an owner by assignment of the patents in suit identified in paragraph 9 below and manufactures OxyContin® in the United States.

8. Upon information and belief, defendant KV Pharmaceutical Company (“KV”) is a corporation organized and existing under the laws of the State of Delaware, having a place of business at 2503 South Hanley Road, St. Louis, Missouri 63144. Upon information and belief, KV is currently doing business in this Judicial District by making and shipping into this Judicial District, or using, offering to sell or selling, or causing others to use, offer to sell or sell, pharmaceutical products.

### **THE PATENTS IN SUIT**

9. Plaintiffs are the lawful owners of all right, title and interest in and to the following United States patents, including all right to sue and to recover for past infringement thereof, which patents contain one or more claims covering the composition and method of use of OxyContin®:

A. United States Patent No. 5,508,042, entitled “CONTROLLED RELEASE OXYCODONE COMPOSITIONS” (“the ‘042 patent”), a copy of which is attached hereto as Exhibit A, which was duly and legally issued on April 16, 1996, naming Benjamin Oshlack, Mark Chasin, John J. Minogue and Robert F. Kaiko as the inventors;

B. United States Patent No. 5,656,295, entitled “CONTROLLED RELEASE OXYCODONE COMPOSITIONS” (“the ‘295 patent”), a copy of which is attached hereto as Exhibit B, which was duly and legally issued on August 12, 1997, naming Benjamin Oshlack, Mark Chasin, John J. Minogue and Robert F. Kaiko as the inventors;

C. United States Patent No. 5,549,912, entitled “CONTROLLED RELEASE OXYCODONE COMPOSITIONS” (“the ‘912 patent”), a copy of which is attached hereto as Exhibit C, which was duly and legally issued on August 27, 1996, naming Benjamin Oshlack, Mark Chasin, John J. Minogue and Robert F. Kaiko as the inventors.

### **KV’S ANDA**

10. Upon information and belief, KV submitted Abbreviated New Drug Application (“ANDA”) No. 78-506 to the U.S. Food and Drug Administration (“FDA”), under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)), seeking approval to engage in the commercial manufacture, use and sale of Oxycodone Hydrochloride Extended-Release Tablets 30 mg and 60 mg (“KV’s Tablets”), a generic version of Purdue’s OxyContin®, before the expiration of the ‘042, ‘295 and ‘912 patents.

11. Upon information and belief, KV's ANDA contains a "Paragraph IV" certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) alleging that the '042, '295 and '912 patents are invalid, unenforceable and/or will not be infringed by the commercial manufacture, use or sale of KV's Tablets.

12. In a letter dated January 4, 2007 addressed to the plaintiffs, KV sent "notice" with respect to its 30 mg and 60 mg Tablets and the '042, '295 and '912 patents under 21 U.S.C. § 355(j)(2)(B)(ii) ("KV's first 30 mg and 60 mg notice"). The plaintiffs received KV's first 30 mg and 60 mg notice on or about January 9, 2007.

13. In a letter dated January 9, 2007 addressed to the plaintiffs, KV sent a further "notice" with respect to its 30 mg and 60 mg Tablets and the '042, '295 and '912 patents under 21 U.S.C. § 355(j)(2)(B)(ii) ("KV's second 30 mg and 60 mg notice"). The plaintiffs received KV's second 30 mg and 60 mg notice on or about January 11, 2007.

14. KV's notices do not provide any valid basis for concluding that the '042, '295 and '912 patents are invalid, unenforceable and/or not infringed.

15. Upon information and belief, the composition and method of use of KV's Tablets are covered by one or more claims of the '042, '295 and '912 patents.

16. Upon information and belief, KV's submission of its ANDA was an act of infringement of the '042, '295 and '912 patents under the United States Patent Law, 35 U.S.C. § 271(e)(2)(A).

17. Upon information and belief, KV's commercial manufacture, use, sale and/or offer for sale of its Tablets would infringe, contribute to the infringement of, and induce the infringement of one or more claims of the '042, '295 and '912 patents.

18. Upon information and belief, KV has been aware of the existence of the '042, '295 and '912 patents, and has no reasonable basis for believing that KV's Tablets will not

infringe the '042, '295 and '912 patents, thus rendering the case "exceptional," as that term is used in 35 U.S.C. § 285.

19. The acts of infringement by KV set forth above will cause plaintiffs irreparable harm for which they have no adequate remedy at law, and will continue unless enjoined by this Court.

WHEREFORE, plaintiffs pray for judgment:

A. Adjudging that KV has infringed the '042, '295 and '912 patents, and that the commercial sale, offer for sale, and/or manufacture of KV's Tablets would infringe, induce infringement of, and contribute to the infringement of the '042, '295 and '912 patents;

B. Adjudging, pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of KV's ANDA No. 78-506, under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)), to be a date which is not earlier than the last date of expiration of the '042, '295 and '912 patents;

C. Preliminarily and permanently enjoining, pursuant to 35 U.S.C. §§ 271(e)(4)(B) and 283 and Rule 65, Fed. R. Civ. P., KV, its officers, agents, servants, employees, parents, subsidiaries, divisions, affiliate corporations, other related business entities and all other persons acting in concert, participation or in privity with it, and its successors and assigns, from any commercial manufacture, use, offer to sell or sale within the United States, or importation into the United States, of any drug product that infringes the '042, '295 and '912 patents;

D. Declaring this an exceptional case and awarding plaintiffs their attorneys fees, as provided by 35 U.S.C. §§ 271(e)(4) and 285; and

E. Awarding plaintiffs such other and further relief as this Court may deem just and proper.

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